K062138

OCT - 5 2006

ATTACHMENT VIIII - 510(k) SUMMARY

Applicant: Mölnlycke Health Care US, LLC
5550 Peachtree Parkway Suite 500
Norcross, GA 30092

Contact Person: Steven Dowdley, Director of Regulatory Affairs
Tel.: 678-250-7930
Fax: 678-250-7986

Device Name:
Proprietary Name: BioExam Powder Free, Sterile Nitrile Examination Glove
Common Name: Exam Glove (CFR 880.6250)
Classification: Class I

Predicate Device : Powder Free Nitrile Exam Glove (K000868)

Device Description:
Class I sterile nitrile examination glove, powder free and meeting all requirements of ASTM D3578-99, ASTM 6124-97, and ISO 11137, Part 2, Sterilization of Health Care Products.

Intended Use of the Device:
This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

Technological Characteristics of the Device:

	ASTM D3578-99	**Powder Free Colored Blue – Nitrile Examination Gloves Nonsterile, K000868**	**Powder Free Colored Blue –Nitrile Examination Gloves Sterile**
Overall Length:	230mm Minimum	240mm minimum	280 mm minimum
Width:	S: 80mm ±-10mm M: 85mm±-10mm L: 110mm ±-10mm XL: 120mm±-10mm	Small 80mm ±-10mm Medium 90mm±-10mm Medium-Large 105mm±-10mm Large 111mm±-10mm X-Large 120mm±-10mm	Small 80mm ±-10mm Medium 90mm±-10mm Medium-Large 105mm±-10mm Large 111mm±-10mm X-Large 120mm±-10mm
Palm Thickness:	0.08mm minimum	0.09 – 0.13mm minimum	0.08 mm min.
Finger Thickness:	0.08mm minimum	0.10 – 0.14mm minimum	0.08 mm min.
Tensile Strength:	14 MPa Before 14 MPa After Aging	16 MPa Before Aging 14 MPa After Aging	14 MPa minimum before aging 14 MPa minimum after aging
Ultimate Elongation:	700% Before Aging 500% min After Aging	700% Before Aging 500% minimum After Aging	500% minimum before aging 400% minimum after aging (meeting ASTM D6319 requirements

Protein	Zero/Below detection limit using ASTM D 6499
Barrier	Passed ASTM F 1671
Integrity	AQL 0.65 (ASTM D7161)
Leak Acceptance	AQL 0.65 (ASTM D7161)

Biocompatibility:
In vitro biocompatibility testing was completed by NAMSA to determine the cytotoxic end-point of the test device extract. The results showed that the sterile gloves passed all testing (ISO Closed Patch Sensitization and ISO Skin Irritation).

Microbiological viral penetration testing of protective clothing material intended to protect against blood borne pathogen hazards was also conducted. All acceptance criteria was met for both the negative and positive control samples. The negative control samples were negative for viral penetration, and the positive control samples were positive for viral penetration.

Comparison to the Predicate:
The BioExam Sterile Powder Free Nitrile Examination Glove is substantially equivalent in safety, design and indication for use to the powder free nitrile examination gloves previously cleared under K000868.

Total Residual Powder Content & Presence of Cornstarch:
Residual Powder Content – 0.4-1.6mg/glove
Presence of Cornstarch - negative

Clinical Data:
Clinical data is not needed required for gloves.

Conclusion:
The data provided in this 510(k) summary concludes BioExam Powder Free Sterile Nitrile Exam Glove substantially equivalent to the previously clear device under K000868.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Steve Dowdley
Director of Regulatory Affairs
Molnlycke Healthcare, Incorporated
5550 Peachtree Parkway, Suite 500
Norcross, Georgia 30092

OCT - 5 2006

Re: K062138
Trade/Device Name: Sterile Powder Free, Blue Nitrile Examination Glove
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: September 22, 2006
Received: September 25, 2006

Dear Mr. Dowdley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

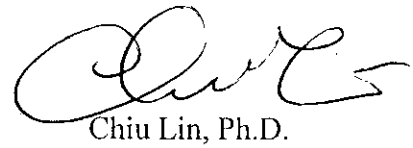
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Molnlycke Heath Care US, LLC
5550 Peachtree Parkway, Suite 500
Norcross, GA 30092
Sterile Powder Free, Blue Nitrile Examination Glove 510(k)

3.0 Indications for Use Statement:

INDICATION FOR USE

Applicant: Molnlycke Heath Care US, LLC

510(k) Number: K062138

Device Name: Sterile Powder Free, Blue Nitrile Examination Glove

Indication for Use:

This is a medical glove to be worn on the hand of health care and similar personnel to prevent contamination between health care personnel and the patient.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use _____ Or Over-The-Counter _____X_____

Per 21 CFR 801.109

Sheila A. Murphy M.D. 11/3/06

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K062138